



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| | | | | |
|---|-------------|----------------------|--|-------------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/826,880 | 04/19/2004 | Joel M. Blatt | XMET-1035039 | 9880 |
| <div>7590 Laurie A. Axford Gordon & Rees LLP Suite 1600 101 West Broadway San Diego, CA 92101</div> | | | <div>EXAMINER NGUYEN, BAO THUY L</div> | |
| | | | <div>ART UNIT 1641</div> | <div>PAPER NUMBER</div> |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | | MAIL DATE | DELIVERY MODE |
| 3 MONTHS | | | 03/07/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/826,880 | | BLATT ET AL. | |
| | Examiner | | Art Unit | |
| | Bao-Thuy L. Nguyen | | 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 1-50 and 61-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-50 and 61-67 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 06 February 2007.
2. Claims 51-60 are examined herein.

Priority

3. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

This application is claiming the benefit of prior-filed nonprovisional application No. 08/512,844 under 35 U.S.C. 120, 121, or 365(c). Copendency between the current application and the prior application is required. Since the applications are not copending, the benefit claim to the prior-filed nonprovisional application is improper. Applicant is required to delete the reference to the prior-filed application from the first sentence(s) of the specification, or the application data sheet, depending on where the reference was originally submitted, unless applicant can establish copendency between the applications.

The parent application 08/512,844 was abandoned on 10 October 1999 and officially revived on 21 September 2004; while the instant application 10/826,880 was filed on 19 April 2004. Therefore, the two applications were not copending.

Specification

4. The disclosure is objected to because of the following informalities:

The heading of claims dated 02 February 2007 lists the serial number of 11/371,725. This is incorrect. The instant application number is 10/826,880.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 51-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 51 is vague and indefinite because there is no description of the second reagent nor a description of what is in the second reaction product in the reference zone. Furthermore, claim 51 is unclear with respect to the description of "a corresponding test zone detectable response". Is this a zone separate from the test zone

having non-diffusively bound first reagent? What is in the "corresponding test zone" and how is it retained there?

Claim 51 is also confusing with respect to the description or lack thereof of "a corresponding reference zone detectable response". Is this a zone that is separate from the reference zone? What is in this zone and how is it retained there?

What does the reagent in the reference zone bind to so that it can provide a reference?

The recitation of "the reaction zone detectable response" lacks antecedent support.

Claim 56 is vague. Where are these reagents disposed on the porous member? In what zone? What is their function? The recitation of "diffusively or non-diffusively bound" is vague. What is it? Is it bound or is it not bound? The meets and bounds of this claim cannot be ascertained for the reasons stated.

Claim 57 is vague because the location of the sample filtration member is not clearly recited.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 51-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fitzpatrick et al (US 5,451,504) in view of Robinson et al (US 5,856,203).

Fitzpatrick discloses a device and method comprising a pathway of three zones, a first mobilization zone, a second trap zone, and a third detection zone, arranged so that the first and the third zone are spaced apart by the second zone. Labeled receptor specific for the analytes is provided on the first zone, the second zone has immobilized ligand and the third zone provides for detection a receptor-analyte complex which positively correlates with the presence of analyte in the sample. See column 2, lines 26-36. Fitzpatrick teaches that any arrangement that provides a series of three or more zones in communication so that liquid will move from the first zone through the second into the third zone may be used. Column 3, lines 27-37. In addition to the basic three zones, the sample pathway may also include an application zone for applying sample, and an absorbent zone which facilitates movement of the sample through the zones as well as a control zone. See column 3, lines 37-49. Labels are selected from colloidal gold, dye polymers, colored latex particles, or enzyme. See column 4, lines 26-34 and column 8, lines 30-37. Receptors can be monoclonal or polyclonal antibodies. See column 6, lines 26-35. Fitzpatrick also discloses an application zone that functions as a filter for removing undesirable particles from a sample. See column 9, lines 30-32.

Membrane materials are nylon, coated plastic, silica gel, paper, or other porous material. See column 2, lines 57-68.

Fitzpatrick differs from the instant invention in failing to teach at least one reference zone.

Robinson, however, discloses sensor devices for assaying ligands comprising a measurement zone having immobilized a first specific binding partner, the measurement zone also contains a first known amount of a labeled second specific binding partner for the ligand under assay; a second discrete reference zone having immobilized a first specific binding partner for the ligand under assay and also contain a known amount of ligand analogue and separately contains a second known amount of a labeled second specific binding partner for the ligand. Robinson also discloses that the device may contain one or more additional reference zone, each containing different known amount of labeled specific binding partner. See column 2, line 18-57 and column 6, lines 43-57. Robinson discloses devices such as test strips, biosensors or flow-through devices. See column 3, lines 12-19.

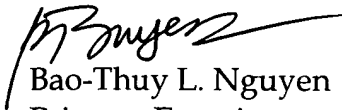
Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Fitzpatrick by including multiple reference zones such as taught by Robinson because having a plurality of reference zones provides means for calibrating the assay as part of the assay procedures without using additional steps.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Wednesday from 8:00 a.m. -4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641

2/26/07